

PROTOCOL TITLE:

SURVEY TO ASSESS THE EFFECTS OF THE COVID-19 PANDEMIC ON SYMPTOMATOLOGY, TREATMENT AND MEDICAL CARE FOR CARDIOVASCULAR PATIENTS

Principal investigator

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PROJECT SUMMARY

In patients with cardiovascular (CV) conditions, most hospital admissions in the emergency room are caused by decompensation of the previous etiological condition (v.g. ischemic heart disease, heart failure etc.) leads to an increase in hospital re-entry mortality, anxiety disorders and hospital costs. The objective of this research is to establish symptomatic, therapeutic, and behavioral modifications in patients cardiovascular patients

Material and method

This study will consist of lifting a survey through a designated questionnaire that will qualify dimensions: Symptomatology, Therapeutics and Medical Care. Patients with cardiovascular conditions will be included. consecutively, over 18 years of age, of both genders. The CV diagnosis, based on two groups 1) Ischemic Cardiopathy (CAD), for one or more history Myocardial infarction, Hemodynamic study with obstructive coronary artery injury, Coronary artery angioplasty with balloon and/or stenting and coronary revascularization surgery (CABG). 2) Heart failure here are criteria of the European Society of Cardiology (ESC criteria): Clinical pattern, laboratories, and cardiac imaging. We will conduct telephone interview (if permitted by the face-to-face health authority) in the initial phase consists of the Principal Investigator's Name Presentation, from the Heart Failure Center, your consent and settlement will be requested, we will proceed to read you the questions, at the end again the Investigator will be appointed with his phone number, thanks and conclusion with quarterly and annual monitoring

PROJECT OBJECTIVES:

Primary:

Secondary(s):

Purpose

Apply a survey to identify changes in symptoms, therapeutic scheme, medical care in cardiovascular patients.

Overall goal

Establish symptomatic, therapeutic, and medical care modifications in sick patients cardiovascular

Specifics Objectives

To determine the impact of changes on:

- Functional Class
- therapeutic conducting
- Need for medical care
- Clinical disturbances
- Emotional distress

Introduction

Cardiovascular diseases severely impact public health services, as it generates high rates of patients, hospitalization and mortality, which directly impact survival, quality of life^{1,2}. In Mexico, Verdejo and collaborators³ demonstrated that the cardiovascular conditions that most impact are: coronary ischemic disease (CAD), Heart Failure (HF), High Blood Pressure (HTA) and Atrial Fibrillation (AF). They felt that the economic impact produced is significantly high.

The prevalence of cardiovascular disease is increasingly important, prevalence can be close to 28% in the population over the age of 40^{1,2}. In recent decades it has been observed that this prevalence tends to rise for every decade, ranking around 45-63% in all over-70s⁴. It causes high demand for medical care, admission to emergency departments and hospitalization.^{1,2,4}

In the United States of America, the record of CAD mortality during the twentieth century and the first decade of the 21st century, I lead on any other pathology^{2,4}. Despite all the medical, technological and financial efforts in countries such as Mexico, protocols have been created for the integral management and control of this pathology⁵, CAD mortality is the highest in the last three decades and affects 33% of Mexico's population.⁵

On the other hand, HF, this pathology associated with the malfunction of the heart, which impairs the mechanism to maintain a continuous cardiac systemic infusion on a regular basis. Patients have an unfavorable prognosis when they have reached the symptomatic phase^{6,7}. About 50% of patients diagnosed with Heart failure die in the first 4 years in clinical follow-up⁴, this figure is 90% when severe HF has been diagnosed⁷. Characteristically, HF has an inadequate role in emptying and/or filling cardiac ventricular chambers leading to a circulatory deficit to meet the body's metabolic and energy demands^{8,9}. Heart Failure shows a wide range of clinical presentations, ranging from the completely asymptomatic subject, to absolute physical disability in advanced stages, pulmonary edema and cardiogenic shock. Causing the disease to decline in quality of life, high economic impact on the individual, on family life and in the health institutions responsible for the care of the population⁷⁻⁹. Finally, with a significant reduction in life expectancy and high hospital mortality^{8,10}.

Drug treatment of HF has achieved, since over the decades, survival has improved, the rate of hospitalizations, such as quality of life^{5,9}. It is recognized that an HF patient ingests 7 or more drugs a day which can complicate therapeutic follow-up such as adherence to them⁹⁻¹⁰. The therapeutic agents recognized in the treatment of HF are: Angiotensin-converting enzyme inhibitors, (ACEI), angiotensin receptor-blocking agents (ARB), beta blockers (BB), Diuretics, mineralocorticoid blockers, and CV therapeutics anticoagulants, antiplatelet agents, Lipid lowering agents, antiarrhythmic, anti-ischemic, glucose-reducing agents. With this survey we aim to evaluate the modification of the use of such agents.

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Since the end of 2019, there have been reports in Asia of the increase in the number of patients with Acute Respiratory Syndrome (ARDS)), subsequently, it was associated that the causal agent is a variety of coronavirus recognizing the pathology mediated by this pathology with COVID-19¹¹⁻¹³.

COVID-19 infection causes direct and indirect myocardial effects. It is recognized that intra-myocardia action there are viral mechanisms associated with the tremendous activation of the immune system¹³. It is postulated, after the progression in replication and spread of the virus through blood circulation or the lymphatic system, a severe spread of myocytes coexists^{11,14}. An extraordinary systemic inflammatory response could mediate a severe myocardial injury. Producing, focal or global inflammation of the myocardial, necrosis. This is clinically translated as ventricular dysfunction and tachyarrhythmias, chest pain associated with changes in the electrocardiogram and abnormalities in wall motility¹²⁻¹⁴. Acute myocardial dysfunction (especially in cardiovascular patients) may be associated with a severe inflammatory or toxic response of COVID-19¹¹⁻¹⁴

Justification

Patients with CV and HF pathology have a high risk of morbidity and mortality from any bacterial or viral infection. In the context of the coVID-19 joint we consider that this group of patients are at risk compared to the population free of CV pathologies. That is why, we consider the need to evaluate during the period of highest elevation of the pandemic through dimensions: Symptomatology, Therapeutics and Health Care. survey, with the aim of observing significant changes. Which will be compared in other time periods.

Purpose

Apply a survey to identify changes in symptoms, therapeutic scheme, and medical care in cardiovascular patients.

Research question

Will there be symptomatic, therapeutic, and medical care modifications in cardiovascular patients during the COVID-19 pandemic?

Principal outcome

Establish symptomatic, therapeutic, and medical care modifications in cardiovascular patients.

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Targets specifics

To determine the impact of changes on:

- Functional class
- Therapeutic behavior
- Need for medical care
- Clinical disturbances
- Emotional distress

Scope of research

Publication in scientific journal

Variables

- Symptomatology
- Medical care
- Therapeutic

Conceptual definition

Symptomatology

The questionnaire has specific clinical questions, simple to answer, which aim to place the clinical conditions of the sick. Likewise, the functional classification of the New York Heart Association (NYHA) is a valid instrument for patients carrying cardiovascular pathologies, especially for CAD and HF, practical and easy to use. Through four degrees. Regarding the clinical interrogation where the location of each patient in that construct will be determined.

Medical Care

Determined by the need for each patient to seek medical advice. It will be quantified in: medical care, and in the emergency department by decompensation and hospitalization by decompensation.

Therapeutic

Recording of any change or modification in the previously indicated therapist.

Operational definition

VARIABLES (SIGNS)	OPERATIONAL DEFINITION	SCALE	SOURCE
Angina	Diffuse, oppressive pain in the chest which may radiate to the upper left limb, jaw, and epigastrium.	Class I (great efforts) Class II (Slight limitation of normal activity) Class III (Moderation of Regular Activity) Class IV (Any effort generates angina)	Survey/File
Myocardial infarction Acute Coronary Ischemic Syndrome	Set of pathologies involving an inadequate contribution of O ₂ to the myocardium, generating an ischemic process.	With ST segment elevation, No ST segment elevation, Unstable Angina	Survey/File
Edema	Quantification of swollen ankles in both pelvic limbs	Presence or absence	Survey/File
Health status	Assessment of the condition of degree of improvement-worsening of your cardiovascular disease by individual consideration of each patient.	It is valued in two dimensions: -Likert scale and visual analog _scale	Survey/File
Mortality	Absence of vital signs and hospital death statement.	Dichotomous: Presence or absence	Survey/File
Physical limitation	Reduced ability to do simple daily activities: walking, running, doing work at home, bathing, or self-dressing	Dichotomous: Presence or absence	Survey/File
Dyspnea	New event or increased feeling of shortness of breath from minimal to great efforts.	Dichotomous: Presence or absence	Survey/File
Orthopnea	Decubitus dyspnea and/or increased use of two or more pillows.	Dichotomous: Presence or absence	Survey/File

VARIABLES (SIGNS)	OPERATIONAL DEFINITION	SCALE	SOURCE
Paroxysmal nocturnal dyspnea	Dyspnea that suddenly occurs to decubitus.	Dichotomous: Presence or absence	Survey/File
Medical care	Need to seek medical advice.	Remote presence or not	Survey/File
Emergency room admission	Medical intervention in emergency room by decompensation or need to go to emergency medical service	Dichotomous: Presence or absence	Survey/File
Hospitalization	Hospital care for worsening or disease decompensation that warrants hospitalization	It is valued in five dimensions: -Heart failure, -Another heart cause, -Another non-cardiac cause, -COVID, -None	Survey/File
Cardiovascular therapeutic modification	Changes in the previously established therapeutic scheme.	Dichotomous: Presence or absence	Survey/File
Emotional distress	Assessment of the condition of excessive and continuous level of concern and fear in everyday situations.	It is valued in two dimensions: -Likert Scale and -Visual analog Scale	Survey/File
NYHA CLASS	Functional classification of the New York Heart Association of the functional fitness of cv sufferers	Inconveniences to: 1 unchanged 2. To great efforts 3. Moderate efforts 4. Minimal effort	Survey/File

Hypothesis

Ho: There will be no clinical changes in cardiovascular disease.

H1: There will be clinical changes in cardiovascular disease

Design

Case survey. Basal sample (June 2020) with three quarterly follow-ups (October 2020, February 2021 and June 2021). Non interventional. Nested in a cohort

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Sample

For the calculation of the sample size we declare an alpha error of 0.05, the power of the association of 20% and a change difference of 21%, thus we determined 70 patients per group, with 10% for losses. Our sample consists of a total of 140 subjects.

Sampling

Non-probabilistic- consecutive

Inclusion criteria

1. Over 18 years of age.
 2. Both genders.
 3. Patients able to interact with the medium, understand and answer the questioning.
 4. Defined History of Ischemic heart disease (one or more criteria):
 - History of myocardial Infarction,
 - History of coronary obstructions,
 - History PTCA or stent procedures
 - History of myocardial revascularization surgery. (any diagnostic criteria)
- or
5. Clinical diagnostic criteria for Heart Failure:
 - Signs and symptoms on the physical exam.
 - Laboratories: NTP-proBNP: >125pg/ml. and/or BNP: >35pg/ml.
 - Left ventricle ejection fraction (LVEF) <40% through any imaging method: Ultrasound, MRI, computed axial tomography and nuclear medicine.
 6. Accept and settlement to participate in the survey

Exclusion criteria

1. Impairment to contact patients.
2. Physical and cognitive impairment that prevents optimal interrogation.
3. Cultural barriers involving limitation of communication (languages, dialects, reading and writing, etc.).
4. Not wish to participate.

Procedures

Development of research processes:

1. It will consist of the phone search for cardiovascular disease. The initial process is the full-name identification of the researcher, Reason for the call is to conduct the survey.
2. We proceed to read the paragraph settlement.
3. In case of acceptance:

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4. It will read question by question, detailing doubts for a correct obtaining of answers, without involving with the nature of what is settled by the patient.
5. At the end of the farewell, the main investigator's phones are appreciated and offered.
6. With the possibility of conducting face-to-face interviews, when the authority deems them appropriate, we will proceed to invite patients to follow up, as well as, to sign the informed consent.
7. Every three months the same survey will be conducted to determine the impact of any movement caused by the temporality.
8. At the same time, the database will be automatically populated, which will be moved to the STATA system for the respective analysis.
9. Data mining will be carried out.
10. Followed by the statistical process.
11. Development and writing of the document for publication.
12. Send to scientific journal.
13. Publication

Finally, reports will be followed up to the ethics and research committee.

Data analysis

A survey will be lifted through the electronic platform, that will determine a document in ASCII code, therefore we will perform the analysis of the data will be carried out by means computational statistical programs (STATA).

Statistical Analysis

Initially we will use a univariable approach, which will consist of determining the distribution, bias, and kurtosis of each variable, we declare Smirnov test for normality test

Demographic and baseline characteristics of the both groups were compared using the Student t test or Chi square test. Continuous variables were reported as means (standard deviation). Categorical variables were reported as numbers (percentage). The odds ratio (OR) with 95% confidence interval (CI95%) were calculated by Chi square test. We consider a two-sided p value below 0.05 to be statistically significant. Analyses were performed with STATA statistics software, version 8.0 (Stata Corp, College Station, TX, USA).

Ethical considerations

Prior to the start of the survey, the researcher will read the first paragraph where the patient verbally manifests the settlement to participate in this investigation. For quarterly follow-ups in the same way the patient verbally manifests the settlement to continue participating in this investigation.

In accordance with the provisions of the health authority, federal or local, the first possibility that a face-to-face visit could be brought will apply the format of informed consent, with the criteria of the official Mexican standard for informed consents (NOM-004-SSA3-2012). Patients will decide to continue their participation.

All researchers state that :

- The clinical notes and data collected during the intervention will be used exclusively for teaching purposes (clinical reports, clinical sessions), preparation of doctoral thesis, research, publication in sources of a scientific and professional nature.

- We will use confidentially and ethically the material and/or information contained in each case. Removing personal identification of patients from any source of information.

If necessary, the researchers may refer me to the emergency department of the National Institute of Cardiology. Doubts, questions, or emergencies related to the study will be contacted by Dr. Eduardo Chuquiure Valenzuela by phone: (56666566 0 5554017407)

Funding / Financing

For this study we declare no funding.

Human Resources

Principal investigator designed the protocol concept, performed statistics, correction, and correction of the same.

Doctors Emmanuel Tapia López, Daniel García Romero were interns under the mentorship of Dr. Eduardo Chuquiure Valenzuela, currently performing the residency of Internal Medicine in the designated hospitals, they collaborate in clinical, research and analysis activities for the Heart failure Center, in this protocol they will help the telephone interviews and writing the manuscript. performed statistics, correction, and correction of the same.

Dr. Alan Fuentes Mendoza was a resident of clinical cardiology under the mentorship of Dr. Eduardo Chuquiure Valenzuela, currently performing work as a clinical cardiologist at the designated hospital: He collaborates in clinical, research and analysis activities for Heart failure Center, protocol will assist in telephone interviews and writing of the manuscript. performed statistics, correction, and correction of the same.

Elyz Cortez and Alejandra Marin are interns in social service under the tutelage of Dr. Eduardo Chuquiure Valenzuela.

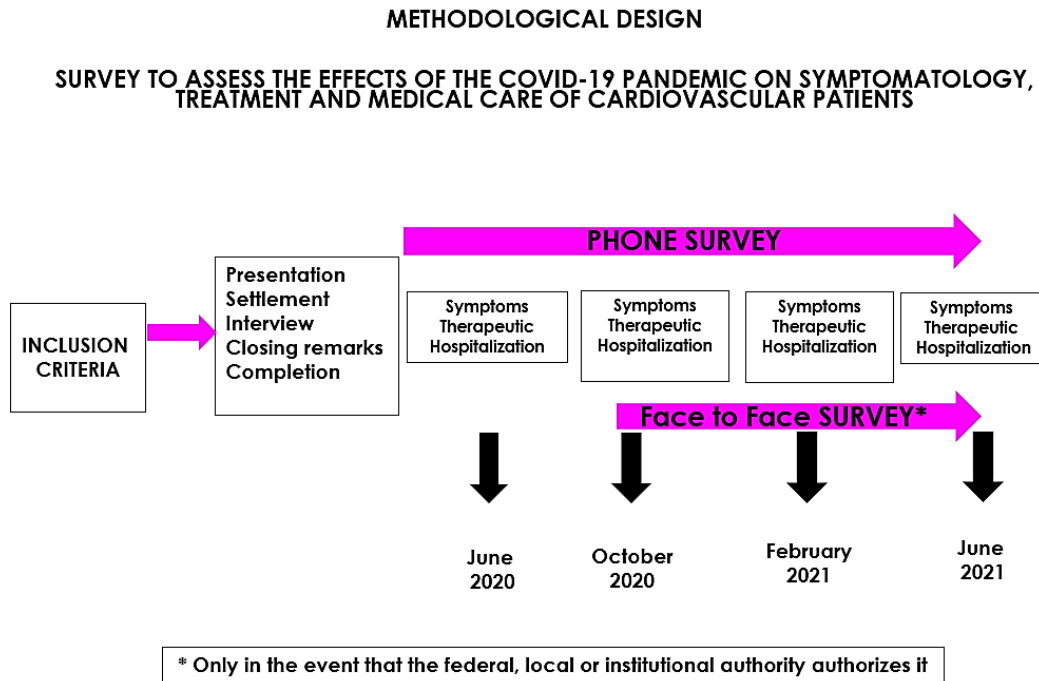
Dr. Laura Rodríguez Chávez, Dr. Nilda Espíndola Zavaleta, Dr. Gerardo Vieyra Herrera, Dr. Enrique Lopez Mora , are affiliated cardiologists, who participate in the revision of the writing for publication.

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DESIGN AND PROCEDURES



INFORMED CONSENT
FOLLOW-UP PROGRAM FOR CARDIOVASCULAR PATIENTS (English traduction)

Mexico City, date ____ / ____ / ____

Patient Name _____

institutional registration _____ Date of birth _____

I freely state that I have been informed (a) by the lead investigator, broadly, understandably and to full satisfaction, of the characteristics and objectives of the

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I authorize and consent to Dr. Eduardo Julián José Roberto Chuquiure Valenzuela to perform the procedure. Due to the circumstances of the pandemic by COVID-19 I acknowledge that previously my consent was by telephone, this one ratifies the follow-up.

Under this understanding, I recognize that the lead researcher, explained to me the information detailed below, which contains, among other things, the nature of the procedure plan and the benefits I will be able to obtain from accessing the program.

This program consists of:

- Knowledge and management of your illness
- Importance of adherence to treatment
- Optimal medication management
- Determine the standard of morbidities.
- Recognize the pattern of clinical symptoms
- Establish the pattern of clinical signs
- Know the modalities of therapeutic schemes.

1. I give my consent for me as a patient to provide information from my file.

2. I understand that my participation is extremely important.

3. I consent to the clinical notes and data collected during the intervention being used by the physicians responsible for teaching purposes (clinical reports, clinical sessions), elaboration of doctoral thesis, research, publication in scientific and professional sources.

4. I understand that the physicians in charge are responsible for the confidential and ethical use of the material and/or information contained in each case. Removing personal identification of patients from any source of information. This will always respect the right to confidentiality of information.

5. I understand that if necessary, those responsible may refer me to another health service as a patient.

6. I understand that my consent to participation is voluntary, and that I may withdraw at any time and when I deem it necessary, not without first setting out my reasons.

7. I understand that there is the possibility that the intervention program or the procedure will continue according to the proposed plan.

8. I also understand that there are no identified risks or possible complications arising from this program.

Any questions or emergencies related to the study contact the phone: (55) 732911.

PATIENT'S NAME AND SIGNATURE

RESPONSIBLE NAME AND MEDICAL SIGNATURE

Date: _____

NAME AND SIGNATURE OF RESPONSIBLE FAMILY MEMBER

Address: _____

Kinship: _____

Date: _____

NAME AND SIGNATURE OF WITNESS 1

Address: _____

Kinship: _____

Date: _____

NAME AND SIGNATURE OF WITNESS 2

Address: _____

Kinship: _____

Date: _____

Activities Chronogram

	Gant's diagram													
	2020							2021						
Activity	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul
Protocol design.	X													
Database design.	X													
Data collection.	X				X				X				X	
Preparation of theoretical framework.	X													
Data mining		X				X				X				X
Participation in congresses.												X		
Elaboration of research articles.		X												X

QUESTIONAIRE (English traduction)
Symptomatology, Treatment, Daily Activities and Emotional Distress for Cardiovascular patients Survey (STRATA)

ITEM	Text to read patients	Answer
Initial	<p>Dear participant, the principal investigator, Dr Eduardo Chuquiure Valenzuela from The National Institute of Cardiology Is studying patients with cardiovascular conditions. In this phone interview, we propose to ask some questions that will also be asked to other patients like you</p> <p>We just want to know your opinion about the current situation of your illness, the symptoms of medical care as your treatment.</p> <p>At any time, you can freely request the end of the survey.</p> <p>Researchers are committed to making all responses confidential, for scientific research only</p>	<p>A) I Agree B) I decline</p>

GENERAL

ITEM	Text to read patients	Answer
1	Registry number	
2	Names	
3	First name	
4	In the last four weeks? How your health status qualified? Where 1= worst and 10 Excellent	from 1 to 10 (Analog-visual scale)
5	In the last four weeks? Rated your health status perception	a. Excellent b. Good c. No change d. Poor e. Worst
6 Optative	Cause of death HEART FAILURE: Related to acute HF decompensation CARDIAC: Any cardiovascular condition except heart failure NON-CARDIAC Any causes for non-cardiovascular diseases.	a.- Heart failure b.- Cardiac c.- Non-Cardiac d.-COVID-19 e.- None
7 Optative	Date of death	Day, month, year

DAILY ACTIVITIES PERCEPTIONS

ITEM	Text to read patients	Answer
8A	In the last four weeks? Please, mention if you a perceived limitation on : -Jogging	a.- Yes b.- No
8B	In the last four weeks? Please, mention if you a perceived limitation on : -Carrying > 5Kg.	a.- Yes b.- No
8C	In the last four weeks? Please, mention if you a perceived limitation on : -Walking more 1 hour	a.- Yes b.- No
8D	In the last four weeks? Please, mention if you a perceived limitation on : - Housework duties	a.- Yes b.- No
8E	In the last four weeks? Please, mention if you a perceived limitation on : - Regular work activities.	a.- Yes b.- No
8F	In the last four weeks? Please, mention if you a perceived limitation on : -Climbing stairs (two steps)	a.- Yes b.- No
8G	In the last four weeks? Please, mention if you a perceived limitation on : - Walking more 500 meters	a.- Yes b.- No
8H	In the last four weeks? Please, mention if you a perceived limitation on : -Showering yourself	a.- Yes b.- No
8I	In the last four weeks? Please, mention if you a perceived limitation on : -Dressing yourself	a.- Yes b.- No

SYMPTOMS PERCEPTIONS

ITEM	Text to read patients	Answer
9	In the last four weeks? Did you perceive chest pain? (Ischemic related)	a.- Yes b.- No
10	In the last four weeks? Did you perceive shortness of breath?	a.- Yes b.- No
11	In the last four weeks? Did you have needed two or more pillows for shortness of breath?	a.- Yes b.- No (dichotomous)
12	In the last four weeks? Have you been suddenly awakened by shortness of breath ?	a.- Yes b.- No
13	In the last four weeks? Did you perceive ankle swelling?	a.- Yes b.- No
14	In the last four weeks Did you need clinical/medical assistance? Mention one.	a.- None b.- Distance c.- Face to Face
15	In the last four weeks? Did you receive clinical assistance in emergency room (ER) for medical decompensation? Mention one.	a.- Heart Failure b.- Other cardiac c.- Non cardiac d.- COVID-19 e.- None
16	In the last four weeks? Did you have hospitalized for medical decompensation? Mention one.	a.- Heart Failure b.- Other cardiac c.- Non cardiac d.- COVID-19 e.- None

TREATMENT

ITEM	Text to read patients	Answer
17A	In the last four weeks Have you modified your MEDICAL treatment? -ACEI	a.- Yes b.- No
17B	In the last four weeks Have you modified your MEDICAL treatment? -ARB	a.- Yes b.- No
17C	In the last four weeks Have you modified your MEDICAL treatment? -BETABLOCKES	a.- Yes b.- No
17D	In the last four weeks, Have you modified your MEDICAL treatment? -DIURETICS	a.- Yes b.- No
17E	In the last four weeks Have you modified your MEDICAL treatment? -NITRATES	a.- Yes b.- No
17F	In the last four weeks Have you modified your MEDICAL treatment? -SPIRONOLACTONE	a.- Yes b.- No
17G	In the last four weeks Have you modified your MEDICAL treatment? -ASPIRIN	a.- Yes b.- No
17H	In the last four weeks Have you modified your MEDICAL treatment? -LIPID LOWERING AGENTS	a.- Yes b.- No
17I	In the last four weeks Have you modified your MEDICAL treatment? -HYPOGLUCEMICS	a.- Yes b.- No
17J	In the last four weeks Have you modified your MEDICAL treatment? -ANTIARRHYTHMIC	a.- Yes b.- No
17K	In the last four weeks Have you modified your MEDICAL treatment? -OTHER	a.- Yes b.- No

EMOTIONAL DISTRESS

ITEM	Text to read patients	Answer
18	In the last four weeks How your EMOTIONAL DISTRESS perception qualifies ¿ Where 1= worst and 10 Excellent	from 1 to 10 (Analog-visual scale)
19	In the last four weeks Did you consider that your emotional distress perception was associated with any of these limitations?	a.- Heart failure b.- Familiar c.- work d.- COVID-19 e.- None

NYHA Functional class

20	Rate NYHA Functional class Question answered by the interviewer doctor	a.- 1 b.- 2 c.- 3 d.- 4
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CLOSING

Closing	We appreciate your participation. We'll be tracking it over the phone or when possible by face-to-face interview Any questions do not hesitate to contact Dr. Eduardo Chuquiure Valenzuela at 55732911 ext. 30021	
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